REMARKS

The Examiner has maintained the restriction requirement in the present case; therefore, claims 1-38 have been cancelled, without prejudice to filing future divisional applications. Claims 39-46, drawn to methods of preparing a fresh human whole blood sample, are pending in the present case. Claims 39 and 46 have been amended, and claim 42 has been cancelled.

I. Rejections Under 35 U.S.C. §112, First Paragraph

Claims 39-46 stand rejected under 35 U.S.C. §112, first paragraph as allegedly failing to comply with the written description requirement. The Examiner asserts that the specification "lacks a definition for 'fresh'; therefore, it is unclear how this term has been defined."

Applicants respectfully disagree that there is no support in the specification for the terms "fresh human whole blood". These terms have plain meaning and also "must be read in the context of the specification of which they are a part," *Budde v. Harley-Davidson, Inc.*, 250 F.3d 1369, 1379 (Fed. Cir. 2001). Through their consistent use throughout the specification, including the drawings, the terms "fresh human whole blood" are entitled to their common meaning and usage which comports with their use in the context of the specification, which is described herein below.

With regard to the term "whole blood," the data in Fig. 1 shows that certain blood samples utilized to demonstrate the present invention are whole blood samples—the cytogram illustrates that the samples contain whole blood components, namely: red cells, platelets, white cells and plasma. ***See specifically Figure 1***, scatter plot areas by numbers: 10 denotes lysed red blood cell products, 12 denotes lymphocytes, 14 denotes monocytes,

and 16 denotes granulocytes (a copy of Figure 1 is attached herewith for reference). It is clear from these cytograms, that the exemplified blood samples shown in Figs. 1-4 are whole blood samples and that there is support in the specification for the meaning of "whole blood". Additionally, the term "whole blood" is known and understood by those of ordinary skill in the art of blood controls and methods.

Furthermore, numerous descriptions of the samples typically used in the present invention include office, home or veterinary settings-which imply that no processing of the blood sample is taking place in these instances. *See*, paragraph 28:

> The composition may be used for analyzing blood of humans, other mammals, birds, reptiles, or other animals, in either a hospital, veterinary or other clinical or institutional setting.

Similarly the samples are noted as being capable of analysis on numerous commercially available equipment including (paragraph 30):

> The compositions of the present invention may be used alone or in combination with other commercially available lytic reagents, including for example, IMMUNOPREP.TM. (Beckman Coulter), LYSE and FIX (Beckman Coulter), Q-Prep (Beckman Coulter) OPTILYSE (Beckman Coulter), FACS Lyse (Becton Dickinson), ERYTHROLYSE (Serotec), FLOWLYSE (Mallinckrodt), WHOLE BLOOD LYSE KIT (Caltag), UTI-LYSE (Dako), Q-LYSE (BioErgonomics, Inc.), ammonium chloride or the like. Moreover, active ingredients of the above may be substituted for or used in combination with the ingredients of the present compositions.

Note the specific reference to WHOLE BLOOD LYSE KIT (Caltag) and the discussion that any active ingredients of the listed kits could be substituted for or used in combination with ingredients of the present compositions. Thus, taken as a whole, the specification clearly indicates that exemplary blood samples as described and illustrated in the figures are whole blood samples, and while the invention is not limited to whole blood samples, whole blood samples are exemplified and described throughout the specification.

With regard to the term "fresh", applicants point to numerous locations in the specification where the term "fresh" appears:

[0004] For instance, to prepare a sample for fluorescent flow cytometry, according to one conventional practice, a volume of ***fresh sample blood*** is provided, and a suitable amount of a desired fluorochrome labeled antibody is added. The sample and antibody mixture is incubated to allow antibody/antigen bindings to take place.

(031) To prepare a sample for fluorescent flow cytometry, according to one method of the present invention, ***a predetermined volume of fresh sample blood*** is provided, and a suitable amount of the desired fluorochrome labeled monoclonal antibody is added. The sample and antibody mixture is then incubated for a predetermined time (e.g., about 10 to about 30 minutes) at a predetermined temperature to allow antibody and antigen bindings to take place. Sample may then be washed and resuspended as desired.

Applicants also point to the use of the term "fresh" in the specification, drawings, and particularly in the claims of related issued patent U.S. Patent 6,794,152.

Importantly, for commonly used words such as "fresh", the common dictionary meaning of the term is presumed, unless the Applicant acts as his own lexicographer. The Meriam Webster dictionary meaning of the word "fresh" is appropriate and comports with the use of the term throughout the specification:

Main Entry: **[1]fresh**

Function:*adjective*

Etymology: Middle English, from Old French *freis,* of Germanic origin; akin to Old High German *frisc* fresh; akin to Old English *fersc* fresh **1 a : having its original qualities unimpaired**: as (1) **:** full of or renewed in vigor **:** REFRESHED <rose *fresh* from a good night's sleep> (2) **: not stale, sour, or decayed** <*fresh* bread> (3) **:** not faded <the lessons remain *fresh* in her memory> (4) **:** not worn or rumpled <a *fresh* white shirt> **b :** not altered by processing <*fresh* vegetables>.

In the context of the present application, it is clear that the term "fresh blood" means blood "having its original qualities unimpaired," or "not stale, sour, or decayed." Thus, Applicants believe that the statutory provisions of §112, paragraph 1 are fulfilled and request that this rejection be withdrawn.

II. Rejections Under 35 U.S.C. §112, Second Paragraph

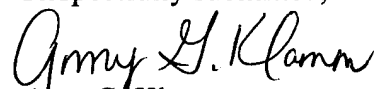
Claims 39-46 stand rejection under 35 U.S.C. §112, second paragraph as allegedly being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The Examiner states that "claims 39 and 46 (mistakenly referred to by the Examiner as 49) are vague with respect to the part b because it is unclear what is meant by 'a fluorescent label associated with a known antibody'." Applicants have amended claims 39 and 46 as suggested by the Examiner.

The Examiner states that claim 42 does not further limit claim 39. Applicants have cancelled claim 42.

Applicants believe that the presently pending claims are in condition for allowance, and respectfully request that they be allowed. The Examiner is encouraged to call the undersigned should any further action be required for allowance.

It is believed that no fees are presently due. Should any fees be required for any reason relating to the enclosed materials, the Commissioner is authorized to deduct said fees from Deposit Account No. 01-2508/12642.0046.DVUS01.

Respectfully submitted,



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